

Application No. 10/802,280

Reply to Office Action

*AMENDMENTS TO THE CLAIMS*RECEIVED
CENTRAL FAX CENTER

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This listing of claims replaces all prior versions, and listings, of claims in the application.

1. (Currently Amended) A method of increasing the bioavailability of the active form of *S*-[2-([1-(2-ethylbutyl)cyclohexyl]carbonyl)amino)phenyl] 2-methylpropanethioate to a patient receiving *S*-[2-([1-(2-ethylbutyl)cyclohexyl]carbonyl)amino)phenyl] 2-methylpropanethioate therapy comprising orally administering to the patient once per day a therapeutically effective amount of *S*-[2-([1-(2-ethylbutyl)cyclohexyl]carbonyl)amino)phenyl] 2-methylpropanethioate in a pharmaceutical composition with food, wherein the food is not part of the pharmaceutical composition.
2. (Original) The method of claim 1, wherein the therapeutically effective amount is about 100 mg to about 1800 mg.
3. (Original) The method of claim 2, wherein the therapeutically effective amount is about 300 mg to about 900 mg.
4. (Original) The method of claim 1, wherein the administration to the patient occurs between about 1 hour prior to consuming food to about 2 hours after consuming food.
5. (Original) The method of claim 4, wherein the administration to the patient is substantially at the same time as the consumption of the food.
6. (Original) The method of claim 4, wherein the administration to the patient is immediately after the consumption of food to up to about 1 hour after the consumption of food.
7. (Original) The method of claim 1, wherein the pharmaceutical composition is in a unit dosage form of a tablet.
8. (Original) The method of claim 7, wherein the tablet comprises about 100 mg to about 1800 mg of *S*-[2-([1-(2-ethylbutyl)cyclohexyl]carbonyl)amino)phenyl] 2-methylpropanethioate.

Application No. 10/802,280

Reply to Office Action

9. (Original) The method of claim 8, wherein the tablet comprises about 300 mg of S-[2-([1-(2-ethylbutyl)cyclohexyl]carbonyl)amino]phenyl] 2-methylpropanethioate, and the therapeutically effective amount is about 300 mg to about 900 mg.

10. (Original) The method of claim 1, wherein the administration results in an increase in the maximum plasma concentration of the active form of S-[2-([1-(2-ethylbutyl)cyclohexyl]carbonyl)amino]phenyl] 2-methylpropanethioate as compared to the administration of S-[2-([1-(2-ethylbutyl)cyclohexyl]carbonyl)amino]phenyl] 2-methylpropanethioate without food.

11. (Original) The method of claim 1, wherein the pharmaceutical composition is provided to a patient in a container associated with prescribing information that advises the patient that the pharmaceutical composition is to be administered with food.

12. (Original) The method of claim 11, wherein prescribing information further advises the patient that the administration of S-[2-([1-(2-ethylbutyl)cyclohexyl]carbonyl)amino]phenyl] 2-methylpropanethioate in a pharmaceutical composition with food results in an increase of the maximum plasma concentration of the active form of S-[2-([1-(2-ethylbutyl)cyclohexyl]carbonyl)amino]phenyl] 2-methylpropanethioate as compared to the administration of S-[2-([1-(2-ethylbutyl)cyclohexyl]carbonyl)amino]phenyl] 2-methylpropanethioate under fasted conditions.

13. (Original) The method of claim 11, wherein the prescribing information further advises the patient to administer the pharmaceutical composition between about 1 hour prior to consuming food to about 2 hours after consuming food.

14. (Original) The method of claim 13, wherein the prescribing information further advises the patient to administer the pharmaceutical composition substantially at the same time as consuming food.

15. (Original) The method of claim 13, wherein the prescribing information further advises the patient to administer the pharmaceutical composition immediately after consuming food to up to about 1 hour after consuming food.

Application No. 10/802,280

Reply to Office Action

16. (Currently Amended) A method of increasing the extent of absorption of the active form of *S*-[2-([1-(2-ethylbutyl)cyclohexyl]carbonyl)amino)phenyl] 2-methylpropanethioate as measured by the active form concentration attained in the blood stream over time in a patient in need of a therapeutic effect thereof comprising orally administering to the patient once per day a therapeutically effective amount of *S*-[2-([1-(2-ethylbutyl)cyclohexyl]carbonyl)amino)phenyl] 2-methylpropanethioate in a pharmaceutical composition with food, wherein the food is not part of the pharmaceutical composition.

17. (Original) The method of claim 16, wherein the therapeutically effective amount is about 100 mg to about 1800 mg.

18. (Original) The method of claim 17, wherein the therapeutically effective amount is about 300 mg to about 900 mg.

19. (Original) The method of claim 16, wherein the administration to the patient occurs between about 1 hour prior to consuming food to about 2 hours after consuming food.

20. (Original) The method of claim 19, wherein the administration to the patient is substantially at the same time as the consumption of the food.

21. (Original) The method of claim 19, wherein the administration to the patient is immediately after the consumption of food to up to about 1 hour after the consumption of food.

22. (Original) The method of claim 16, wherein the pharmaceutical composition is in a unit dosage form of a tablet.

23. (Original) The method of claim 22, wherein the tablet comprises about 100 mg to about 1800 mg of *S*-[2-([1-(2-ethylbutyl)cyclohexyl]carbonyl)amino)phenyl] 2-methylpropanethioate.

24. (Original) The method of claim 23, wherein the tablet comprises about 300 mg of *S*-[2-([1-(2-ethylbutyl)cyclohexyl]carbonyl)amino)phenyl] 2-methylpropanethioate, and the therapeutically effective amount is about 300 mg to about 900 mg.

Application No. 10/802,280

Reply to Office Action

25. (Currently Amended) A method for decreasing the activity of cholesteryl ester transfer protein (CETP) in a patient, which comprises orally administering to the patient once per day a therapeutically effective amount of S-[2-([1-(2-ethylbutyl)cyclohexyl]carbonyl)amino]phenyl] 2-methylpropanethioate in a pharmaceutical composition with food, wherein the food is not part of the pharmaceutical composition.

26. (Original) The method of claim 25, wherein the therapeutically effective amount is about 100 mg to about 1800 mg.

27. (Original) The method of claim 26, wherein the therapeutically effective amount is about 300 mg to about 900 mg.

28. (Original) The method of claim 25, wherein the administration to the patient occurs between about 1 hour prior to consuming food to about 2 hours after consuming food.

29. (Original) The method of claim 28, wherein the administration to the patient is substantially at the same time as the consumption of the food.

30. (Original) The method of claim 28, wherein the administration to the patient is immediately after the consumption of food to up to about 1 hour after the consumption of food.

31. (Original) The method of claim 25, wherein the pharmaceutical composition is in a unit dosage form of a tablet.

32. (Original) The method of claim 31, wherein the tablet comprises about 100 mg to about 1800 mg of S-[2-([1-(2-ethylbutyl)cyclohexyl]carbonyl)amino]phenyl] 2-methylpropanethioate.

33. (Original) The method of claim 32, wherein the tablet comprises about 300 mg of S-[2-([1-(2-ethylbutyl)cyclohexyl]carbonyl)amino]phenyl] 2-methylpropanethioate, and the therapeutically effective amount is about 300 mg to about 900 mg.

34. (Currently Amended) A method for the treatment of a cardiovascular disorder in a patient, which comprises orally administering to the patient once per day a therapeutically effective amount of S-[2-([1-(2-

Application No. 10/802,280

Reply to Office Action

ethylbutyl)cyclohexyl]carbonyl]amino)phenyl] 2-methylpropanethioate in a pharmaceutical composition with food, wherein the food is not part of the pharmaceutical composition.

35. (Original) The method of claim 34, wherein the cardiovascular disorder is selected from the group consisting of cardiovascular disease, coronary heart disease, coronary artery disease, hypoalphalipoproteinemia, hypercholesterolemia, and atherosclerosis.

36. (Original) The method of claim 34, wherein the therapeutically effective amount is about 100 mg to about 1800 mg.

37. (Original) The method of claim 36, wherein the therapeutically effective amount is about 300 mg to about 900 mg.

38. (Original) The method of claim 34, wherein the administration to the patient occurs between about 1 hour prior to consuming food to about 2 hours after consuming food.

39. (Original) The method of claim 38, wherein the administration to the patient is substantially at the same time as the consumption of the food.

40. (Original) The method of claim 38, wherein the administration to the patient is immediately after the consumption of food to up to about 1 hour after the consumption of food.

41. (Original) The method of claim 34, wherein the pharmaceutical composition is in a unit dosage form of a tablet.

42. (Original) The method of claim 41, wherein the tablet comprises about 100 mg to about 1800 mg of S-[2-([1-(2-ethylbutyl)cyclohexyl]carbonyl]amino)phenyl] 2-methylpropanethioate.

43. (Original) The method of claim 42, wherein the tablet comprises about 300 mg of S-[2-([1-(2-ethylbutyl)cyclohexyl]carbonyl]amino)phenyl] 2-methylpropanethioate, and the therapeutically effective amount is about 300 mg to about 900 mg.

44. (Currently Amended) A kit comprising a pharmaceutical composition comprising a therapeutically effective amount of S-[2-([1-(2-

Application No. 10/802,280

Reply to Office Action

ethylbutyl)cyclohexyl]carbonyl]amino)phenyl] 2-methylpropanethioate and a pharmaceutically acceptable carrier, prescribing information, and a container, wherein the prescribing information includes advice to a patient regarding administration once per day of S-[2-([1-(2-ethylbutyl)cyclohexyl]carbonyl]amino)phenyl] 2-methylpropanethioate in a pharmaceutical composition with food, wherein the food is not part of the pharmaceutical composition.

45. (Original) The kit of claim 44, wherein the prescribing information states that the administration of S-[2-([1-(2-ethylbutyl)cyclohexyl]carbonyl]amino)phenyl] 2-methylpropanethioate with food improves bioavailability.

46. (Original) The kit of claim 44, wherein the therapeutically effective amount is about 100 mg to about 1800 mg.

47. (Original) The kit of claim 46, wherein the therapeutically effective amount is about 300 mg to about 900 mg.

48. (Previously Presented) The kit of claim 44, wherein the prescribing information includes advice to a patient regarding administration of S-[2-([1-(2-ethylbutyl)cyclohexyl]carbonyl]amino)phenyl] 2-methylpropanethioate in a pharmaceutical composition between about 1 hour prior to consuming food to about 2 hours after consuming food.

49. (Previously Presented) The kit of claim 48, wherein the prescribing information includes advice to a patient regarding administration of S-[2-([1-(2-ethylbutyl)cyclohexyl]carbonyl]amino)phenyl] 2-methylpropanethioate in a pharmaceutical composition substantially at the same time as the consumption of the food.

50. (Previously Presented) The kit of claim 48, wherein the prescribing information includes advice to a patient regarding administration of S-[2-([1-(2-ethylbutyl)cyclohexyl]carbonyl]amino)phenyl] 2-methylpropanethioate in a pharmaceutical composition immediately after the consumption of food to up to about 1 hour after the consumption of food.

Application No. 10/802,280

Reply to Office Action

51. (Original) The kit of claim 44, wherein the pharmaceutical composition is in a unit dosage form of a tablet.

52. (Original) The kit of claim 51, wherein the tablet comprises about 100 mg to about 1800 mg of *S*-[2-([1-(2-ethylbutyl)cyclohexyl]carbonyl)amino)phenyl] 2-methylpropanethioate.

53. (Original) The kit of claim 52, wherein the tablet comprises about 300 mg of *S*-[2-([1-(2-ethylbutyl)cyclohexyl]carbonyl)amino)phenyl] 2-methylpropanethioate, and the therapeutically effective amount is about 300 mg to about 900 mg.